Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Respiratory Assist Devices With Back-up Rate

JUNE 2001
OEI-07-99-00440

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EXECUTIVE SUMMARY

PURPOSE

To determine if the bi-level respiratory assist device with a back-up rate receives frequent and substantial servicing.

BACKGROUND

The Omnibus Reconciliation Act of 1993 (OBRA 1993) amended the Social Security Act to exclude ventilators that are "either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices" from the "frequent and substantial servicing" payment category. The Health Care Financing Administration (HCFA) has proposed that the bi-level respiratory assist device with a back-up rate be reassigned to the capped rental category in accordance with the exclusion implemented by OBRA 1993, but has not yet completed action on this proposal.

Under the frequent and substantial payment category, suppliers are paid an established monthly rental fee as long as the device is medically necessary. Under the capped rental payment category, suppliers are paid a monthly rental fee for a stipulated amount of time at which point either Medicare purchases the machine on behalf of the beneficiary or the beneficiary continues to rent the device on their own. The impact of reclassifying the device would be to reduce Medicare reimbursement for the use of this device.

In order to help determine the appropriate category of DME reimbursement for bi-level respiratory assist devices with a backup rate, the Office of Inspector General conducted a study to determine whether such devices receive frequent and substantial servicing. In order to do this, we selected a stratified random sample from all Medicare claims for this device billed during September 1999. Our final sample consisted of 206 beneficiaries served by 182 suppliers for a response rate of 74 percent.

FINDINGS

Supplier services consist primarily of routine maintenance and patient monitoring

Manufacturers, suppliers, and beneficiaries all report that the services provided to beneficiaries by suppliers consist of routine maintenance, mainly of the equipment's accessories, and monitoring the patient's interface with the machine. None of the suppliers or manufacturers indicated internal servicing as part of the regular servicing protocol.

For most beneficiaries, visits do not meet supplier protocols for frequency

Supplier records reveal and beneficiary survey respondents report that supplier visits do not reflect the frequency stipulated by supplier protocols. Supplier records also indicate that visits are not made on a consistent basis. For example, the number of days between beneficiaries' first and second visits ranges from 1 to 468 days. Although beneficiaries are not receiving consistent visits suppliers continue to receive monthly rental payments intended to cover "frequent and substantial servicing."

Contrary to supplier protocols, the number of beneficiaries receiving visits declines over time

Supplier records indicate that the number of beneficiaries receiving visits decreases over time. While a decrease in the number of visits per beneficiary is expected based on supplier protocols, a decrease in the number of beneficiaries receiving services is not. Eighty-five percent of beneficiaries received a visit in the first quarter after they started using the machine. The number of beneficiaries receiving a visit within the second quarter drops to 59 percent. In fact, almost half of the beneficiaries received their last visit from the supplier within 6 months of receiving their machine. Eight percent of beneficiaries never received a single visit.

Covering the respiratory assist device under capped rental would have saved Medicare $11.5 million annually

Between January 1996 and September 1999, the Medicare program allowed $160 million for bi-level respiratory assist devices with a back-up rate. Under capped rental Medicare would have allowed $117 million for this same time period. This yields a potential savings of $43 million or $11.5 million per year.

RECOMMENDATIONS

HCFA should move the bi-level respiratory assist device with a back-up rate from the frequent and substantial servicing to the capped rental payment category

The HCFA's intention to move the bi-level respiratory assist device with back-up rate from the frequent and substantial payment category to the capped rental payment category appears justified. Beyond capturing savings, our findings indicate that the bi-level respiratory assist device with back-up rate primarily requires routine maintenance and patient monitoring. Further, this level of servicing is not performed frequently nor consistently, often stopping after a short period of time.

Given that the delivery of follow-up services is most intense early on, while the beneficiary adjusts to using and caring for the new equipment, a significant portion of follow-up services would be covered by the monthly payments allowed under the capped

rental payment methodology. These rental payments continue for at least a year after the beneficiary receives the machine.

AGENCY COMMENTS

The HCFA concurred with our recommendation, stating that they plan to move the bi-level respiratory assist device with a back-up rate from the "frequent and substantial servicing" payment category to the "capped rental" payment category. They believe this change is needed to accurately reflect the requirements of Section 1834(a)(3) of the Social Security Act.

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INTRODUCTION

PURPOSE

To determine if the bi-level respiratory assist device with a back-up rate receives frequent and substantial servicing.

BACKGROUND

Part B of the Medicare program pays for the rental or purchase of durable medical equipment (DME) used in the patient's home when deemed medically necessary by a physician. Payments for this equipment are made by Durable Medical Equipment Regional Carriers (DMERCs) based on the following six payment categories:

- Inexpensive or other routinely purchased equipment,
- Items requiring frequent and substantial servicing,
- Customized items,
- DME supplies,
- Oxygen and oxygen equipment, and
- Capped rental items.

In order to help determine the appropriate category of DME reimbursement for bi-level respiratory assist devices with a backup rate, the Office of Inspector General (OIG) conducted a study to determine whether such devices receive frequent and substantial servicing.

Noninvasive Positive Pressure Respiratory Assistance

Noninvasive positive pressure respiratory assistance (NPPRA) is the administration of continuous positive air pressure to a patient using a nasal and/or oral mask. Avoiding the use of a more invasive airway access such as a tracheostomy, NPPRA devices are designed to be used on an "intermittent" basis (i.e. for only part of the day, usually during the hours of sleep). Such devices are non-life supporting and are to be distinguished from invasive ventilation administered via an intubated airway in a patient for whom disruption or failure of ventilatory support would lead to the "imminent demise" of the patient.[1]

[1] Region A DMERC Supplier Manual (Rev. 10, 6/99) Chapter 14.30-2

Medicare covers three types of respiratory assist devices that provide noninvasive positive pressure respiratory assistance therapy:

1. A Continuous Positive Airway Pressure (CPAP) Device (HCPC E0601) provides a single level of continuous positive airway pressure.

2. A Bi-Level Positive Airway Pressure Device **without** a back-up rate (HCPC K0532[2]) delivers adjustable, variable levels of positive air pressure to assist spontaneous respiratory efforts and supplement the volume of air a patient inspires into the lungs.

3. A Bi-Level Positive Airway Pressure Device **with** a back-up rate (HCPCS K0533[3]) also delivers adjustable, variable levels of positive air pressure to assist spontaneous respiratory efforts and supplement the volume of air a patient inspires. In addition to the automated delivery of bi-level air pressure, this device also has a time back-up feature to detect when a patient has stopped or delayed breathing. Whenever "sufficient spontaneous inspiratory efforts fail to occur" the back-up feature ensures that the appropriate amount of air is provided.[4]

The Health Care Financing Administration (HCFA) medical policy regarding these three types of respiratory assist devices became effective October 1, 1999. The policy contains coverage criteria and payment rules, including four therapeutic classifications for which NPPRA is medically indicated and a stipulation that the patient must use the machine at least 4 hours out of every 24 hours to be eligible for Medicare coverage. To assure that the requirements are being met, the prescribing physician must re-certify medical necessity and the beneficiary must certify appropriate levels of usage between 30 to 45 days after receiving the device.

The four therapeutic classifications are: (1) restrictive thoracic disorders, (2) severe chronic obstructive pulmonary disease (COPD), (3) central sleep apnea, and (4) obstructive sleep apnea. Before a bi-level respiratory assist device with back-up rate can be prescribed for any of these conditions, therapy using a CPAP or a bi-level respiratory assist device without a back-up rate must be attempted.

Even though these devices are covered under the same medical policy, they are covered under different reimbursement methodologies. Medicare covers the bi-level respiratory assist device with a back-up rate under the "items requiring frequent and substantial servicing" DME payment category, whereas the CPAP and bi-level respiratory assist device without back-up rate are covered under the "capped rental items" category.

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[2] Prior to October 1, 1999, the HCPCS code was E0452.

[3] Prior to October 1,1999 the HCPCS code was E0453

[4] Region A DMERC Supplier Manual (Rev. 10, 6/99) Chapter 14.30-2

Frequent and Substantial Servicing Payment Category

Items in this category are defined by the Social Security Act to require "frequent and substantial servicing to avoid risk to the patient's health."[5] There are no definitions, within the law or HCFA publications, for "frequent" or "substantial" servicing of DME items in this category, nor is "risk to the patient's health" defined. An indication of Congressional intent regarding items requiring frequent and substantial servicing exists in House Report 101-391 (I), accompanying the Omnibus Budget Reconciliation Act of 1987. It states that "this class of items would include those that are technologically sophisticated and require frequent monitoring or adjustment in order to make sure that they are functioning properly or being properly utilized by the patient."

Payment for equipment under this classification is made on a monthly rental fee schedule computed as set forth in Section 1834(a)(3) of the Social Security Act. Payment continues as long as the equipment is medically necessary. Maintenance to the equipment and any accessories to the equipment are considered to be covered under the monthly rental fee. It is the supplier's responsibility to assure that an appropriate level of servicing is provided by appropriately trained personnel.

There are currently eight items in the "frequent and substantial servicing" category, including volume ventilators, negative pressure ventilators, ultrasonic nebulizers, intermittent positive pressure breathing (IPPB) machines of all types, infusion pumps for uninterrupted administration of epoprostenol, and bi-level respiratory assist device with a back-up rate.

Under the frequent and substantial payment category, the Medicare reimbursement for the bi-level respiratory assist device with a back-up rate has shown a continuous increase since 1996[6]. In 1996, Medicare allowed $34 million for bi-level respiratory assist devices with a back-up rate. Our estimate of total allowed amount for 2000 is $147 million. This represents more than a 300 percent increase over 5 years.

Capped Rental Payment Category

Payment for capped rental items, as established in the Social Security Act, is made on a monthly fee schedule.[7] This fee schedule is equal to 10 percent of the purchase price for the first 3 months and 7.5 percent of the purchase price for each remaining month.[8] In addition to the monthly capped rental fee, Medicare will pay for accessories to the CPAP and bi-level respiratory assist device without a back-up rate, such as a nasal application

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5 Section 1834(a)(3)

6 Our review of Medicare reimbursements for this device only went back to 1996.

7 Section 1834(a)(7)

8 The purchase price is based on a national limited payment amount.

device, headgear, chin strap, tubing, and filters. During the 10th month of continuous rental, the supplier must offer a purchase option to beneficiaries who then have 1 month to make their decision.

If the beneficiary opts not to purchase the equipment, monthly rental payments continue through the 15th month. After 15 months, the supplier must continue to provide the item to the beneficiary without charge to Medicare. The Durable Medical Equipment Regional Carriers will reimburse the supplier a "maintenance and servicing payment" computed as the lower of "a reasonable and necessary maintenance fee established by the Secretary" or 10 percent of the total purchase price for that item. This fee is payable every 6 months, whether servicing is provided or not, beginning 6 months after the 15th rental month.

If the beneficiary accepts the purchase option, Medicare rental payments end after 13 months, and the supplier must transfer the title of the item to the beneficiary. For items that are purchased, payment for maintenance and servicing are made when repairs are "necessary to make the equipment serviceable."[9] This payment is made on the "basis of reasonable charges in the locality for maintenance and servicing."[10]

Reclassification of Respiratory Assist Devices

The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) amended the Social Security Act to exclude certain DME items from the "frequent and substantial servicing" payment category. While IPPB machines and ventilators remained in this category, "ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices" were excluded from the "frequent and substantial servicing" payment category.[11] As a result, HCFA reclassified both the CPAP and the bi-level respiratory assist device without a back-up rate in the capped rental payment category. However, the bi-level respiratory assist device with a back-up rate continues to be reimbursed using the "frequent and substantial servicing" payment methodology.

The HCFA has proposed that the bi-level respiratory assist device with a back-up rate be reassigned to the capped rental category in accordance with the exclusion under Section 1834(a)(3) of the Social Security Act. The HCFA maintains that this type of device was inappropriately classified as an item requiring frequent and substantial servicing. Apparent concerns regarding the impact the exclusion of this item might have on beneficiaries have prompted certain members of Congress to request that HCFA examine

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9 HCFA DME Carrier Manual

10 Social Security Act, Section 1834(a)(7)

11 Public Law 103-66, Subpart D Sec. 13543

the accuracy of the payment category and, in the interim, maintain the current reimbursement methodology for this device.

On June 25, 1999, HCFA sponsored a Public Town Hall Meeting to discuss the exclusion and implications of moving the device to capped rental. At this meeting, industry representatives argued that changing the payment category of this device would significantly reduce the frequency of contact between the provider and the patient and that such a reduction would compromise the quality of care and clinical benefit that patients receive from noninvasive positive pressure respiratory assistance therapy. They argued that the capped rental payment category does not adequately cover the "patient's home-care needs for frequent and substantial servicing of equipment and the routine in-home patient care needed for successful therapy."[12] Further, some physicians expressed that the successful implementation of noninvasive ventilation requires close monitoring by a respiratory therapist and that reimbursement under the capped rental category will not allow vendors to provide such necessary care.

HCFA Coverage of Other Services

Reimbursement for maintenance and servicing of a rented item is considered to be part of the rental fee. This is true regardless of DME payment category. Suppliers are allowed to charge a separate "maintenance and servicing" payment under capped rental, only after the item is purchased or the rental period ends but usage continues.

The HCFA defines "routine periodic servicing" as "testing, cleaning, regulating and checking of the beneficiary's equipment which is not [separately] covered."[13] The HCFA explains that such "routine maintenance" should be the responsibility of the owner of the equipment, rather than by a retailer or some other person who charges the beneficiary, and included in the rental fee. Normally purchasers of DME are given operating manuals which describe the type of servicing an owner may perform to properly maintain the equipment. Hiring a third party to do such work for the convenience of the beneficiary is not covered.

[12] Comments from the Public Town Hall Meeting on medicare Payments for RADs, June 25, 1999

[13] DMERC Carriers Manual, Part 3, Chapter II: Coverage and Limitation, Section 2100.4-B.

METHODOLOGY

Sample Selection

Using the Medicare Part B National Claims History data, we selected a stratified random sample of 300 Medicare claims (corresponding to 300 beneficiaries) for this device billed to Medicare during September 1999. The sample was categorized into two strata.

< Stratum 1: beneficiaries only using the bi-level respiratory assist device with a back-up rate = 150 claims
< Stratum 2: beneficiaries using the bi-level respiratory assist device with a back-up rate and oxygen = 150 claims

The two strata were developed to determine if servicing of the equipment and patient monitoring varied between beneficiaries who use only a respiratory assist device and those who use both the device and oxygen.

We excluded 21 suppliers from our sample as advised by the Office of Investigations, reducing our sample to 279 beneficiaries who received services from 229 suppliers.

Data Collection

We collected data from various sources including Medicare beneficiaries, DME suppliers, DME manufacturers, and national organizations. Data collection occurred from May to June of 2000.

Supplier Surveys. We mailed surveys to the suppliers that provided respiratory assist devices to the beneficiaries in our sample. This survey requested information regarding the frequency with which they visited beneficiaries and the type of service they provided. We requested that suppliers supplement the survey by providing copies of their protocols for equipment servicing and beneficiary monitoring.

To accurately determine the frequency of supplier visits, we requested suppliers provide documentation of all beneficiary contact from January 1999 to the time they received our survey (roughly May 2000). We logged the dates of each contact and whether it was a home visit or performed over the phone. Since it was often not possible to determine the actual services provided during the visits, we were unable to capture the type of service provided during supplier visits from this data source.

Data regarding visits to beneficiaries was linked to the corresponding beneficiaries in our sample. Accordingly, all of the information regarding the frequency of actual supplier visits can be projected to the population. Similarly, the information contained in supplier protocols outlining the expected frequency of visits was linked to the appropriate beneficiaries. The estimates regarding expected patterns of visits have also been projected to the universe.

However, we did not attempt to generalize, to the population of suppliers, data in the supplier survey that was specifically about suppliers. This supplier specific data was not projected since suppliers were not randomly selected, but rather contacted on the basis of their connection to the sampled beneficiaries. In the report, we reference the sample whenever our estimates pertain only to our sample.

Beneficiary Surveys. We completed telephone surveys with 235 of the sampled beneficiaries for an initial response rate of 84 percent. In most cases, we spoke with the sampled beneficiary directly; however, in some situations we spoke with the beneficiary's spouse, family member, or caretaker. Ten of these beneficiaries used DME equipment other than the respiratory assist device under study, decreasing the total to 225 completed beneficiary surveys (81 percent response rate).

The beneficiary surveys inquired about the frequency of equipment usage and supplier home visits. Beneficiaries also were asked to describe the specific services provided during the supplier home visits. In addition, we asked the beneficiaries if they were satisfied with the equipment and whether using the device had improved their quality of life in order to assess whether frequency of visits impacted beneficiary satisfaction or quality of life.

Manufacturer Surveys. We conducted telephone surveys with representatives of the three respiratory assist device manufacturers. The surveys included questions on whether the equipment needs to be serviced, the type of service required, and whether servicing protocols have been established. Our survey also included questions about the content of servicing protocols, the maintenance of equipment servicing records and the existence of protocols regarding patient monitoring services. We requested that manufacturers provide supporting documentation where appropriate.

Accreditations Agency Surveys. We interviewed, via telephone, representatives from the Joint Commission for Accreditation of Healthcare Organizations, the National Association of Home Care, the American Association for Home Care, the American Association for Respiratory Therapy Care, and the Advanced Medical Technology Association. We discussed whether these organizations have established standards or policies regarding the level of servicing for the respiratory assist devices under study and the monitoring of patients who use this equipment.

Final Sample used for Analysis

Analysis relies upon data concerning 206 beneficiaries (74 percent of sample) for whom we could incorporate both the beneficiaries' survey responses and corresponding supplier service records. Supplier service records regarding visits to beneficiaries are used as the primary data source. Information gathered from beneficiary surveys is used to enrich information gathered from suppliers and manufacturers.

All of the data, gathered from various sources, is linked back to individual beneficiaries as the primary sampling unit. Accordingly, beneficiaries serve as the unit of analysis for

all projected figures. All estimates regarding beneficiaries are projected to the population of all beneficiaries using bi-level respiratory assist devices with a back-up rate.

The 206 beneficiaries used in the final analysis were served by 182 suppliers. As previously stated, 10 of the 235 beneficiaries we were able to interview over the phone were not using, nor had they ever used, the bi-level respiratory assist device with a back-up rate. They were excluded from our analysis. Further, 19 beneficiaries were eliminated from the analysis because their suppliers did not return surveys, failed to submit service records, or provided only protocols.

The table below illustrates the final sample. For more detail of beneficiary and supplier samples see Appendix A.

Table 1: Final Sample

Completed Beneficiary Telephone Surveys	235
Completed Beneficiary Surveys with Incorrect durable medical equipment	10
Completed Beneficiary Surveys without Corresponding Supplier Service Records	19
Beneficiary Surveys Used for Analysis	**206**
Supplier Responses Used for Analysis	**182**

We conducted our review in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

Supplier services consist primarily of routine maintenance and patient monitoring

According to our analysis of industry publications, there are two types of equipment servicing potentially required by this device: internal equipment servicing and external equipment servicing. Further, suppliers may provide patient monitoring to ensure proper utilization of the equipment.

Internal equipment servicing requires servicing the internal components of the device to insure proper functioning of the device. We have interpreted this to fall within the definition of "extensive maintenance" that is performed by authorized technicians based on manufacturers' recommendations for broken down components or specialized tests. The HCFA covers such extensive maintenance as "repairs."

External equipment servicing consists of cleaning and replacing device accessories. This type of servicing is encompassed by HCFA's definition of "routine maintenance" which is "testing, cleaning, regulating and checking of the beneficiary's equipment." The HCFA description of "routine maintenance" indicates that maintenance should be the responsibility of the owner of the equipment, rather than of the retailer or some other person who charges the beneficiary.

Patient monitoring includes instructing the patient on the safe and effective use and maintenance of the equipment, including precautions to avoid equipment contamination and patient infection. It may also include diagnostic activities such as obtaining blood samples to determine blood gas values, oximetry, and pulmonary function measurements.

Manufacturers, suppliers, and beneficiaries all report that the services provided to beneficiaries consist of routine maintenance, mainly of the equipment's accessories, and monitoring the patient's interaction with the machine.

Manufacturer and supplier protocols stipulate external equipment servicing and patient monitoring, not internal servicing

All three manufacturers of the respiratory assist device under study report that the equipment itself does not require periodic internal servicing. They do indicate that external servicing is required. These manufacturers define external servicing as changing or cleaning the face mask, filter, or hose. All three manufacturers also indicate that beneficiaries' interface with the equipment should be monitored on a periodic basis.

The supplier protocols we reviewed follow the guidelines set forth by the manufacturers. They too indicate the device requires external and not internal servicing. Further, most suppliers have adopted the definition of external servicing established by the manufacturers.[14] Ninety-six percent of beneficiaries have suppliers who indicate that this device requires "servicing." When asked to explain what type of services they provide, 63 percent of suppliers in our sample indicate that they service the accessories (i.e., check/clean the filter, mask, or tubing) when visiting the beneficiary. Seventy-six percent of suppliers in our sample report checking settings and pressures to ensure beneficiary compliance with respiratory therapy.

Beneficiaries report that supplier visits include routine equipment servicing and patient monitoring, not internal servicing

The majority of beneficiaries report that their equipment was serviced during supplier home visits. When asked to describe the service performed, beneficiaries report that servicing typically includes maintaining or replacing the accessories and adjusting the setting on the respiratory assist device. In particular, beneficiaries who reported that they knew what equipment servicing was performed, indicated the following:

- 75 percent of beneficiaries indicated suppliers brought new supplies,
- 62 percent indicated the suppliers replaced the filter,
- 50 percent indicated suppliers adjusted the equipment based on oxygen saturation test results,
- 17 percent indicated suppliers cleaned the filter, and,
- 15 percent indicated suppliers cleaned the face mask and hose.

Twenty-nine percent of beneficiaries indicated suppliers performed other services such as checking the hours of usage and the settings. One beneficiary indicated that the supplier had visited in order to replace a broken machine. Three other beneficiaries indicated suppliers had performed requested repairs.

Beyond servicing the equipment, almost all beneficiaries report that the supplier representatives provided patient education and orientation to the equipment when the machine was first delivered. This education and orientation includes how to turn the machine on, how to wear the face mask, and how to clean the accessories. Most beneficiaries also report that the supplier representative followed-up with them after the equipment was first delivered. These follow-ups consisted mainly of ensuring that the face mask fit properly, inquiring whether the machine has been helpful, determining the beneficiary's oxygen saturation level, and checking beneficiary vitals.

[14] Eighty-six percent of the suppliers reported that they had used the manufacturer manual in developing their service protocols.

For most beneficiaries, visits do not meet supplier protocols for frequency

We assessed the frequency of supplier visits[15] in relation to the visit schedules established in supplier protocols since no definition of what constitutes "frequent" servicing exists in the law.

Suppliers establish own protocols defining frequency of visits to beneficiaries

In the absence of official policy guidance, individual suppliers have established their own protocols outlining the frequency and content of visits to beneficiaries using the device.[16] Generally, supplier protocols outline a separate initial visit schedule for a specific period of time from the date of delivery. Visits during this initial period are more frequent in order to instruct the patient on how to properly use, care for and clean the equipment. At the end of this period, presumably the patient is comfortable with how to clean and care for the equipment and the supplier transitions into an on-going visit schedule that is less intense. A few suppliers have established a visit schedule that is consistent from the date of delivery.

The supplier protocols we examined reflect a range of frequency for initial contacts made to the beneficiary's home immediately after delivery of the equipment. One supplier merely requires a follow-up phone call to the beneficiary; whereas another protocol requires daily visits for the first week, three visits the second week, two visits the 3rd week and one visit the 4th week.

The duration of the initial visit schedule also varies by supplier. For almost half of the suppliers, the initial visit schedule continues for 3 months from the date of delivery before an on-going schedule is implemented. An additional third of suppliers indicated that their initial visit schedule continues for one month from the date of delivery.

The majority of suppliers in our sample (60 percent) indicated that their on-going schedule consists of quarterly visits to the beneficiary's home. An additional 28 percent of suppliers in our sample indicated that their on-going schedule of visits consists of monthly visits to the beneficiary's home. A few suppliers indicated that their on-going schedule of visits is conducted based on the patient's needs.

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15 While the vast majority of these visits were home visits, a few were performed over the phone.

16 Ninety-one percent of suppliers indicate that they have protocols that cover the frequency and type of servicing for the device. A slightly higher percentage of suppliers indicate that they have protocols that address the education and monitoring of the beneficiaries using this device.

Supplier records revealed inconsistent visits from the supplier that do not reflect supplier protocols

The variation in the number of days between visits does not reflect a pattern of consistent, on-going visits stipulated in supplier protocols. While the median number of days between a beneficiary's first visit and their second visit is 45 days, the number of days between these two visits ranges from 1 to 468 days. This variability appears throughout the time frame captured in our analysis. For example, the number of days between the third and fourth visit ranges between 1 and 352 days. The range between the seventh and eight visits is from 1 to 215 days.

The extreme variability in the frequency of visits makes it difficult to provide an aggregate picture of the services being provided to beneficiaries. Table 2 offers a glimpse of actual visit schedules for 10 randomly selected beneficiaries, providing a sense of how visit schedules differ from beneficiary to beneficiary and for an individual beneficiary over time. This table lays out the number of days between each visit received by the beneficiary. For example, beneficiary one received three visits. There were 468 days between the first and second visit and 13 days between visit two and three.

Table 2: Number of Days Between Visits for a Random Selection of Beneficiaries

	Visit 1 to 2	Visit 2 to 3	Visit 3 to 4	Visit 4 to 5	Visit 5 to 6	Visit 6 to 7	Visit 7 to 8	Visit 8 to 9	Visit 9 to 10
Beneficiary #1	468	13							
Beneficiary #2	52	35	74	32	2				
Beneficiary #3	32	30	32	60	38	82	33	77	77
Beneficiary #4	98	88	14	71	85				
Beneficiary #5	91	75							
Beneficiary #6	3	5	54						
Beneficiary #7	3	10	12	21	58	8	46	11	143
Beneficiary #8	5	2	91	133	82				
Beneficiary #9	93								
Beneficiary #10	54	25	18	53	47	7	15	39	28

Column one of Table 2 represents the number of days between the beneficiaries first visit, typically when the machine is delivered and the patient is educated as to its use and care, and the second visit. As previously stated, most supplier protocols indicate that this second visit should occur very soon after the first visit since the introductory period often requires significant beneficiary support to ensure that they are receiving the maximum benefit from the machine. In Table 2, only three beneficiaries receive a follow-up visit within a week. Only four beneficiaries received a visit within a month. Beneficiary one does not receive a follow-up visit for over a year.

Table 2 also accurately demonstrates that different beneficiaries receive different levels of service. Three beneficiaries appear to be receiving very regular visits, either monthly or quarterly. Other beneficiaries receive much more sporadic visits, and, some beneficiaries stop being visited after 3 or 4 visits. This termination of visits is not due to the fact that the beneficiary stopped using the machine. The average number of months that this sample of beneficiaries used the machine was 15 months. Beneficiary one, for example, has only three visits despite the fact that Medicare records show the beneficiary was using the machine for 24 months and Medicare reimbursed the supplier a monthly rental fee for each of these months.

Majority of beneficiary survey respondents report inconsistent visits from the supplier that do not reflect supplier protocols

Based on the frequency outlined in supplier protocols, we would expect 85 percent of beneficiaries to be visited more frequently initially.[17] Only 48 percent of beneficiaries indicate that the supplier came more often right after the ventilator was first delivered than they do at present. An almost equal number indicated that they did not receive more intense visits initially.

For on-going visits, we would expect, based on an analysis of supplier protocols, that the majority of beneficiaries (60 percent) would be visited on a quarterly basis. However, only 27 percent of beneficiaries reported that they were visited quarterly by the supplier. Although we would expect, at most, 12 percent of beneficiaries to be visited on a less frequent basis than quarterly, more than double that number (30 percent) were visited less than quarterly. Thirty-three percent of beneficiaries reported that they were visited monthly. This is in line with expectations based on supplier protocols.

Beneficiaries visited frequently are more likely to be using oxygen

Beneficiaries receiving more frequent visits are more likely to be on oxygen as well as using the respiratory assist device. Forty-three percent of beneficiary survey respondents

[17] 5.8 percent of protocols called for only 1 follow up visit or phone call, 4.4 percent of initial visits were based on patient needs, and 4.4 percent of protocols made no distinction between initial and on-going schedules.

with oxygen indicated that they were visited on a more than monthly or monthly basis, whereas only 22 percent of beneficiaries not using supplemental oxygen indicated that they were visited on a monthly basis.[18] Only 24 percent of beneficiaries with oxygen were visited less than quarterly, compared to the 57 percent of beneficiaries not on oxygen that reported less than quarterly visits.

For beneficiaries on oxygen, it is difficult to ascertain whether their frequent visits are due to their respiratory assist device or the oxygen equipment. Individuals on oxygen are potentially more likely to receive regular visits because they have two pieces of equipment. Oxygen equipment is rented on a monthly fee schedule similar to the respiratory assist device. Two pieces of equipment can mean two different suppliers performing home visits or one supplier checking both pieces of equipment. Sixty-two percent of beneficiaries on oxygen indicated that the supplier serviced their oxygen equipment at the same time they came to service the ventilator. Eighty-six percent of suppliers in our sample indicated that they serviced other types of equipment at the same time they visited the beneficiary's home to service the respiratory assist device.[19]

Beneficiary satisfaction or quality of life not dependent on frequency of visits

The frequency of supplier visits does not seem to significantly impact beneficiaries' levels of satisfaction with the machine or their sense as to whether the respiratory assist device has improved their quality of life. Overall, 82 percent of beneficiaries believe the bi-level respiratory assist device with the back-up rate has improved their quality of life. This high level of satisfaction remains even when beneficiaries are receiving infrequent visits. Eighty percent of beneficiaries report being either satisfied or very satisfied with their bi-level respiratory assist device despite the fact that they are receiving supplier visits less than quarterly.

Contrary to Supplier Protocols, the Number of Beneficiaries Receiving Visits Declines Over Time

In order to review the pattern of service delivery from the date the beneficiary received the respiratory assist device under study, we reviewed the supplier service records of the 89 beneficiaries who received their device in 1999. For these beneficiaries, we had

[18] No beneficiaries that were without oxygen were visited more than monthly.

[19] Thirty-three percent of suppliers specified that the other equipment was for oxygen. However, 44 percent of suppliers did not specify the type of "other respiratory equipment serviced."

service records[20] from the day they received their equipment through, at least, the subsequent 9 months from their start dates.

We found that the number of beneficiaries receiving visits drops over time, even though suppliers continued to receive monthly rental reimbursements during this time. While a decrease in the number of visits per beneficiary is expected based on supplier protocols, a decrease in the number of beneficiaries receiving services is not.

Almost half of the beneficiaries received their last visit from their supplier within 6 months of receiving their machine. Twenty-one percent of beneficiaries received their last visit from the supplier 3 months from their start date. Eight percent of beneficiaries never received a single visit. Further, 32 percent of the beneficiaries did not receive a visit in the month following their start date.

An analysis of the number of beneficiaries being visited quarterly, reflecting the predominate supplier protocol, also shows that the number of beneficiaries receiving services drops over time. Eighty-five percent of beneficiaries received a visit in the first quarter after they started using the machine. The number of beneficiaries receiving a visit within the second quarter drops to 59 percent. The third quarter only 52 percent of beneficiaries received a visit.

Not only do the number of beneficiaries receiving services drop over time, but the visits these beneficiaries receive do not correspond to suppliers' protocols. Based on our analysis of supplier protocols, 87 percent of these 89 beneficiaries should have been visited in the 6th and 9th month from their start dates. However, less than 25 percent of beneficiaries received visits at these times. The total number of visits received by beneficiaries was also 20 percent below the expected number of visits based on supplier protocols. On average, beneficiaries receive a total of six visits.

One reasonable explanation for the declining number of beneficiaries visited is that over time beneficiaries learn how to properly maintain the respiratory assist device and its accessories, no longer requiring the assistance of a professional. Thus, the supplier may not need to continue visiting these beneficiaries. The Medicare population receiving this device is disproportionately young as compared to the entire Medicare population, and may need less assistance than more elderly beneficiaries. Twenty-seven percent of the users of the respiratory assist device under study are less than 65 years old as compared to 13 percent for the overall Medicare population. On the other end of the spectrum, only 6 percent of respiratory assist device users are 85 years old or older compared to 10 percent in the overall Medicare population.

[20] Suppliers provided service records from January 1, 1999 through May, 2000.

Our data indicates that beneficiaries who are less than 65 years old and qualify for Medicare based on disability rather than age, are more likely to be visited on an infrequent basis. Sixty-four percent of younger, disabled beneficiaries were visited quarterly or even less frequently. Fifty-eight percent of disabled beneficiaries indicated that they receive extremely infrequent visits. In comparison, only 28 percent of aged Medicare beneficiaries (65 years old and older) indicated that they received extremely infrequent visits. Beneficiaries 85 years old or older are the most likely to indicate that they are receiving monthly visits.

For beneficiaries that did receive visits, the use of oxygen might explain why they continue to receive services. Of the beneficiaries who continue to receive visits 6 months after their start date, 84 percent are also receiving oxygen. As previously stated, the use of oxygen makes a beneficiary more likely to be visited more frequently. This analysis indicates that the use of oxygen also makes a beneficiary more likely to continue to receive service over time. However, the purpose of these visits may be more about servicing the oxygen equipment than the respiratory assist device.

Covering the respiratory assist device under capped rental could save Medicare $11.5 million annually

Between January 1996 and September 1999, the Medicare program allowed $160 million for the respiratory assist device under study. We estimate that, if these devices were reimbursed under capped rental methodology, Medicare would have only allowed $117 million. This yields a savings of $43 million for this 45 month period, or $11.5 million annually. This represents approximately 27 percent of the total Medicare allowed payments for this device.

This estimate of savings is extremely conservative. In determining how much Medicare would have been reimbursed under the capped rental category, we used the highest known purchase price for a bi-level respiratory assist device with back-up rate to determine the monthly payments. This price, $6,750, represents the most expensive and least purchased respiratory assist device. We also assumed that no beneficiaries choose to purchase the machine, but rather rented it for the full capped rental period of 15 months. For beneficiaries who do not choose the purchase option and continue to rent the device on their own after the 15 months, the supplier is allowed a semi-annual maintenance fee. This fee was also factored in to our calculations.

The average number of months a beneficiary used the device between January 1996 and September 1999 was 16 months. This is 1 month beyond the length of the allowed rental period under capped rental. In fact, 57 percent of beneficiaries rent the respiratory assist device for less than 15 months. The number of rental months ranged from 1 to 45 months.

On average, the total allowable charge per beneficiary, under the frequent and substantial payment methodology, was $8,557, which is higher than the most expensive retail price for a bi-level respiratory assist device of $6,750. In fact, half of the beneficiaries had allowable charges that exceeded this retail price. These beneficiaries' allowable charges represent 85 percent of the total allowable charges.

Services would be covered under capped rental for the majority of beneficiaries

With both the frequent and substantial servicing payment category and capped rental, the supplier is paid a monthly rental fee for, at least, the first 13 months. Thus, for the first 13 months, suppliers are receiving similar reimbursement with equivalent expectations and should provide service to beneficiaries with respiratory assist equipment in the same manner.

After the 13th month (or the 15th month if the beneficiary chooses not to purchase the equipment under capped rental), the two payment methodologies diverge. Items in the frequent and substantial payment category would continue to be reimbursed a monthly rental fee until such time as the medical necessity ends. Reimbursement for servicing is covered within that fee. Under capped rental, if a beneficiary opts not to purchase the equipment at the end of the capped rental period but rather continue to rent it on their own, the carrier will reimburse the supplier a "maintenance and servicing payment." This fee is payable every 6 months, whether servicing is provided or not. For purchased respiratory assist devices, maintenance and servicing payments are made when repairs are "necessary to make the equipment serviceable."

Given the continued ability of suppliers to bill for periodic servicing, we believe the divergence in payment after the 13th or 15th month should not alter the frequency of contact between the provider and the patient. Fifty-seven percent of beneficiaries utilize a bi-level RAD for less than 15 months. One study found that, on average, beneficiaries utilize respiratory assist devices for less than 12 months.

For those beneficiaries who continue to need the machine beyond the 15 months, our analysis reveals that 76 percent of them did not receive a visit after the 15th month. Of those who continued to use the bi-level RAD and receive visits after 15 months, 83 percent of them were also on oxygen and would be receiving home visits to monitor their oxygen usage.

Beyond the ability to bill for periodic servicing under capped rental, suppliers would also be able to bill separately for the accessories that must be periodically replaced.[21] Currently, they cannot bill for these items under the frequent and substantial payment

[21] Special exception was made for accessories for RADs that were reclassified from frequent and substantial servicing to capped rental under OBRA 1993.

category. The necessary accessories (i.e., face mask, hose, and filter) for the device also are used for other respiratory assist devices and thus already have their own HCPC codes with which to bill HCFA.

RECOMMENDATIONS

HCFA should move the bi-level respiratory assist device with a back-up rate from the frequent and substantial servicing to the capped rental payment category

The HCFA's intention to move the bi-level respiratory assist device with back-up rate from the frequent and substantial payment category to the capped rental payment category appears to be justified. Beyond capturing savings, our findings indicate that the bi-level respiratory assist device with back-up rate primarily requires routine maintenance and patient monitoring. Further, this level of servicing is not performed frequently, often stopping after a short period of time.

The servicing that is being provided does not exceed the monthly coverage that would be covered under capped rental for the first 13 or 15 months. The minimal level of servicing paid for after the 15 months or purchase of the machine corresponds with our finding that visits to beneficiaries drop over time, with almost half of beneficiaries receiving their last visit within 6 months of equipment delivery.

AGENCY COMMENTS

The HCFA concurred with our recommendation, stating that they plan to move the bi-level respiratory assist device with a back-up rate from the "frequent and substantial servicing" payment category to the "capped rental" payment category. They believe this change is needed to accurately reflect the requirements of Section 1834(a)(3) of the Social Security Act.

APPENDIX A

Sample Data

Beneficiary Sample

This table provides detailed information regarding the sample of beneficiaries contacted for the telephone survey.

Sample Category	Stratum 1 Ventilator	Stratum 2 Ventilator And Oxygen	Total
Total Population	4,047	14,288	18,992
Original Sample	150	150	300
Excluded by Office of Investigations	9	12	21
Revised Sample	141	138	279
Deaths	5	2	7
Unable To Contact Beneficiary	21	16	37
Completed Surveys	115	120	235
Incorrect piece of durable medical equipment	5	5	10
No Supplier Surveys	12	7	19
Completed Surveys used for Analysis	98	108	206

APPENDIX A

Sample Data

Supplier Sample

This table lists by category the universe to the total number of completed supplier surveys used for analysis.

Sample Category	Total
Total Suppliers in Sample	250
Excluded by Office of Investigations	21
Revised Total	229
Did Not Return Surveys	23
Completed Surveys	206
No Beneficiary Phone Surveys	24
Completed Surveys Used for Analysis of Supplier Sample	182

APPENDIX B

Confidence Intervals for Selected Statistics

The following table shows the point estimates, sample sizes and 90 percent confidence intervals for selected statistics in the order that they appear in the report. These calculations account for the stratification of the sample as described in the methodology.

Statistic	Point Estimate	n	90 Percent Confidence Interval
Percentage of beneficiaries that indicated suppliers brought new supplies during their visits	75.4 %	120	68% to 83%
Percentage of beneficiaries that indicated suppliers replaced filter	61.9%	120	54% to 70%
Percentage of beneficiaries that indicated suppliers adjusted the equipment based on oxygen saturation test	50.4 %	120	42% to 58%
Percentage of beneficiaries that indicated suppliers cleaned the filter	16.8 %	120	11% to 23%
Percentage of beneficiaries that indicate suppliers cleaned the face mask and hose	14.7%	120	9% to 20%
Percentage of beneficiaries that indicated that the supplier visited more frequently initially	48.4 %	197	42% to 55%
Percentage of beneficiaries reporting quarterly visits	26.7 %	197	21% to 33%
Percent of beneficiaries reporting visits less than quarterly	31.5 %	197	26% to 37%
Percent of beneficiaries reporting monthly visits	33.1%	197	27% to 39%

APPENDIX B

Confidence Intervals for Selected Statistics (cont.)

Statistic	Point Estimate	n	90 Percent Confidence Interval
Percent of beneficiaries who did not receive a single visit the entire nine months	7.6%	89	3% to 12%
Percent of beneficiaries who did not receive a visit the month following their start date	32%	89	23% to 41%
Percent of beneficiaries receiving visits in the first quarter after their start date	85.4%	89	78% to 92%
Percent of beneficiaries receiving visits in the second quarter after their start date	58.9%	89	49% to 69%
Percent of beneficiaries receiving visits in the third quarter after their start date	51.9%	89	42% to 62%
Percent of beneficiaries receiving bi-level RAD in 1999 with no visits in the 6th month	76.8 %	89	69% to 85%
Percent of beneficiaries receiving bi-level RAD in 1999 with no visits in the 9th month	77.3%	89	69% to 85%
Percent of beneficiaries who utilize bi-level RAD for less than 15 months.	56.9%	206	50% to 63%
Percentage of beneficiaries, using the bi-level RAD beyond 15 months, who did not receive a visit after 15 months.	76%	94	68% to 84%
Percentage of beneficiaries, using the bi-level RAD beyond 15 months and receiving visits after 15 months, who are also on oxygen.	83.3%	21	74% to 93%

APPENDIX C

Results of Hypothesis Testing

The following tables show the results of the hypothesis testing conducted in our analysis. We used the chi-square statistic to evaluate statistical significance since the variables we were analyzing were categorical.

Frequency of Supplier Visits by Oxygen					
	Visited More than Monthly	**Visited Monthly**	**Visited Quarterly**	**Visited Less than Quarterly**	**Don't Know how often visited**
Without Oxygen	0%	21.5%	19.3%	57%	2.1%
With Oxygen	6.7%	36.5%	28.9%	24.0%	3.8%

Significant at the 0.0000 level, DF=4

Frequency of Supplier Visits by Age					
	Visited More than Monthly	**Visited Monthly**	**Visited Quarterly**	**Visited Less than Quarterly**	**Don't Know how often visited**
Less than 65 years old	8.3%	23.9%	39.5%	24.7%	3.7%
65- 74	2.2%	38.1%	23.9%	35.6%	0%
75-84	4.4%	34.4%	17.5%	36.4%	7.3%
Greater than or equal to 85	12.0%	39.9%	36.0%	12.0%	0%

Significant at the .05 level, DF = 4

APPENDIX C

Results of Hypothesis Testing

Frequency of Visits by Medicare Status					
	Visited More than Monthly	**Visited Monthly**	**Visited Quarterly**	**Visited Less than Quarterly**	**Don't Know how often visited**
Aged	6.0%	35.3%	27.5%	27.7%	3.5%
Disabled	0%	22.0%	16%	58.0%	4.0%

Significant at the 0.0000 level, DF=10

APPENDIX D

Non-Response Analysis

A consideration in survey analysis is that the results may be biased if non-respondents are significantly different from respondents. To determine whether a difference exists in this survey, we compared the two groups, respondents and non-respondents, by age and oxygen usage. We chose these variables since our analysis of respondents showed they had an impact on the frequency of visits, a core concern of the evaluation.

Our analysis showed no statistically significant difference between respondents and non-respondents with respect to age. There was a statistically significant difference between respondents and non-respondents with respect to oxygen usage. We found that beneficiaries on oxygen had a higher response rate (77 percent) compared to non-respondents on oxygen (68 percent). The computed chi-square statistic (2.78) is statistically significant at the 90 percent confidence level. This indicates a potential for bias in the results.

In order to ascertain the impact of the response rate on frequency of visits, we undertook an analysis of the non-respondents. Assuming that non-respondents would have answered the same as respondents, we imputed non-respondents' likely answers regarding frequency of visits based on the distribution represented by similar respondents. The inclusion of non-respondents did not alter the findings presented. For example, we found that 36.54 percent of beneficiaries on oxygen were visited monthly. Had we included non-respondents, the number of beneficiaries on oxygen that were visited monthly would have been 36.57 percent. This difference is within the confidence interval of our original estimate of 8 percent. Thus, we found no statistical evidence of bias based on oxygen usage.

APPENDIX E

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administrati

Deputy Administrator
Washington, D.C. 203

DATE: JAN 26 2001

TO: Michael F. Mangano
Acting Inspector General

FROM: Michael McMullan
Acting Deputy Administrator

SUBJECT: Office of the Inspector General (OIG) Draft Report "Respiratory Assist Devices With Back-up Rate," (OEI-07-99-00440)

We appreciate the OIG's efforts in this inspection as well as the opportunity to comment on the issues raised in the above-referenced report.

OIG found that supplier services are not "substantial," rather they consist of external routine maintenance and patient monitoring. OIG also found that for most beneficiaries, visits are not "frequent" and do not reflect supplier protocols. Additionally, OIG reports that 75 percent of beneficiaries that obtained a respiratory assist device in 1999 were no longer receiving visits after six months. Finally, according to OIG, covering the respiratory assist device under "capped rental" would have saved Medicare $11.5 million annually without risk to beneficiaries.

We agree with the findings and overall conclusions of this report. OIG's evidence presents strong and convincing arguments for moving the bi-level respiratory assist device with a back-up rate from the "frequent and substantial servicing" to the "capped rental" payment category and we plan to do so. This change is needed to accurately reflect the requirements of section 1834(a)(3) of the Social Security Act and to prevent millions of dollars in erroneous expenditures.

APPENDIX F

Related Office of Inspector General Reports

Usage and Documentation of Home Oxygen Therapy (OEI 03-96-00090)

Medicare Payments for Pressure Reducing Support Services (OEI 02-95-00370)

Oxygen Concentrator Services (OEI-03-91-01710)